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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,634	01/30/2001	Steven W. Herring	32943/KMO/A97	9937

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EXAMINER	
MOHAMED, ABDEL A	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/772,634	HERRING ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/3/04 has been entered.

ACKNOWLEDGMENT OF AMENDMENT, REMARKS AND STATUS OF THE CLAIMS

2. The amendment and remarks filed 5/3/04 are acknowledged, entered and considered. In view of Applicant's request claims 1, 3, 6, 11 and 18-21 have been amended. Claims 1-30 are now pending in the application. The previous rejection under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicant's amendment and remarks filed 5/3/04. Also, the previous rejections under 35 U.S.C. 102(b) for claims 1-5, 7-12, 15, 19 and 20 and 35 U.S.C. 103(a) for claims 6, 13, 16-18 and 21 over the prior art of record are withdrawn in view of Applicant's amendment which limits the above claims to a limitation of "without further heating of the formed complex". However, the previous rejections for claims 22-24 and 26-29 under 35 U.S.C. 102(b) and under 35 U.S.C. 103(a) for claims 25 and 30 over the prior art are maintained for the reasons of record (See below).

NEW GROUND OF REJECTIONS

The following are new ground of rejection necessitated by Applicant's amendment.

CLAIMS REJECTION-35 U.S.C. § 112 1st PARAGRAPH

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 1 and 18-21 as amended on 5/3/04 contain new matter because the original specification does not appear to support "without further heating of the formed complex". The specification on page 2, lines 25 to 28 states that "If desired, the blood protein can be subjected to one or more viral inactivation steps prior to lyophilization, and preferably prior to complexing with the HPαCD. After lyophilization, preferably the blood protein is heated to a temperature and for a time sufficient to inactivate any viral contaminants". There is no indication that the lyophilized blood complex does not require the heating, rather, on lines 26 to 28, the specification clearly states that after lyophilization, preferably the blood protein is **heated** to a temperature and for a time sufficient to inactivate any viral contaminants (See also Examples 2-4 in

the instant specification). Thus, independent claims 1 and 18-21 have no support for the limitation **without further heating of the formed complex** from the original disclosure because there is no disclosure in the specification as now claimed. Thus, Applicant respectfully requested to either cancel all unsupported subject matter or to show where such subject matter has support from the original disclosure.

CLAIMS REJECTION-35 U.S.C. § 112 2nd PARAGRAPH

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 1-21 and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1 and 18-21 are indefinite and confusing in the recitation "without further heating of the formed complex" because it is not clear when the formed complex is not further heated? Is it before or after adding the mixture (i.e., blood protein solution) or before or after lyophilizing the solution? Further dependent claims 3-6, which depend on claim 1 require the steps further comprising heating the blood protein solution, and as such there is no proper antecedent basis in independent claim 1 and also the phrase (i.e. heating the blood protein solution of claim 3) is contradictory with the limitation of claim 1 which requires avoiding heating of the formed complex. Thus, appropriate clarification is required.

Claims 28 and 30 recite the limitation "the product" in line 1. There is insufficient antecedent basis for this limitation in claim 26, or claim 28 or claim 30.

Claim 29 recites the limitation "the process" in line 1. There is insufficient antecedent basis for this limitation in claim 26, or claim 29.

5. It is noted that Applicant has amended independent claims 1 and 18-21 to recite the limitation "without further heating of the formed complex". Because of this limitation, the prior art rejections for claims 1-5, 7-12, 15, 19 and 20 under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) rejection for claims 6, 13, 16-18 and 21 are withdrawn. However, if the limitation (i.e., without further heating of the formed complex) is removed from the above claims, the prior art rejections of 35 U.S.C. 102(b) and 103(a) will be reinstated. Nevertheless, the previous rejections for claims 22-24 and 26-29 under 35 U.S.C. 102(b) and under 35 U.S.C. 103(a) for claims 25 and 30 over the prior art are maintained for the reasons of record.

CLAIMS REJECTION-35 U.S.C. § 102(b)

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-24 and 26-29 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/39761.

The patent of WO 97/39761 as discussed in the abstract, summary of the invention and claims 1, 2 and 4-6 discloses a blood protein product comprising a lyophilized solution of a stable complex protein and hydroxypropyl-α-cyclodextrin (claim 22), wherein the hydroxypropyl-α-cyclodextrin is present in an amount ranging from about 0.5% wt/vol. to about 15% wt/vol. (claim 23); from about 1% wt/vol. to about 12% wt/vol. (claim 24); or a stabilized blood protein solution comprising a complex of the blood protein and hydroxypropyl-α-cyclodextrin (claim 26), wherein the hydroxypropyl-α-cyclodextrin is present in an amount greater than about 3% wt/vol. (claim 27); from about 0.5% wt/vol. to about 15% wt/vol. (claim 28); and from about 1% wt/vol. to about 12% wt/vol. (claim 29). Thus, the prior art discloses the claimed product of stabilized blood protein solution, and in the absence of evidence to the contrary or specific structural limitations, the claimed product disclosed by the reference anticipate product claims 22-24 and 26-29 as drafted.

CLAIM REJECTIONS-35 U.S.C. § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25 and 30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/39761.

The reference WO 97/39761 as discussed in 102(b) rejection above, discloses a blood protein product comprising a lyophilized solution of a stable complex protein and hydroxypropyl-α-cyclodextrin (claim 22), or a stabilized blood protein solution comprising a complex of the blood protein and hydroxypropyl-α-cyclodextrin (claim 26). The reference differs from claims 25 and 30 in not teaching the use of blood protein, which is fibrinogen. Although, the preferred and exemplified blood protein of the reference is FVIII which was stabilized and the solubility of FVIII was enhanced, however, the reference teaches or suggests that other kind of blood proteins can be used and/or incorporated for the same purposes and cites the blood proteins which are included, but are not limited to are albumin, FII, FVII, FVIII, FIX, FX and X_a, fibrinogen, antithrombin III, transferin, haptoglobin, gamma globulins, fibronectin, protein C, protein S, thrombin and C1-inhibitor. Thus, in view of the above, the selection of specific blood

protein (i.e., fibrinogen) is within the ordinary skill of the art to which this invention pertains. Hence, in view of this, the subject formulation may be used in combination with other condition to provide a wide variety of various blood proteins or may be tailored for specific type of blood protein (i.e., fibrinogen). Therefore, the claimed specific blood protein which is fibrinogen, which fall within the scope of the prior art would have been prima facie obvious from said prior art disclosure to a person of ordinary skill in the art at the time the invention was made. Applicants claims are directed to optimization of an "art recognized variable" which is well within the purview of one of ordinary skill in the art, In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Thus, the teachings of the prior art makes *prima facie* obvious the claimed invention's stabilizing product of a blood protein solution such as fibrinogen by adding hydroxypropyl-α-cyclodextrin and lyophilizing the solution to from a lyophilized protein/hydroxypropyl-α-cyclodextrin complex or product thereof, absent of sufficient objective factual evidence or unexpected results to the contrary.

CONCLUSION AND FUTURE CORRESPONDENCE

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272-0955. The examiner can normally be reached on Monday through Friday from 5:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Jon P. Weber, Ph.D.
Primary Examiner

Mohamed/AAM

July 7, 2004